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Attorney Docket No. 9025-7

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Surwit *et al.*
Serial No.: 09/480,432
Filed: January 11, 2000
For: APPARATUS AND METHODS FOR MONITORING AND MODIFYING ANTI-COAGULATION THERAPY OF REMOTELY LOCATED PATIENTS

Group Art Unit: 3626
Confirmation No.: 4307
Examiner: Bleck, Carolyn M.

Date: February 17, 2004

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION--37 C.F.R. § 1.192)

1. Transmitted herewith, in triplicate, is the APPEAL BRIEF for the above-identified application, pursuant to the Notice of Appeal filed on **December 19, 2003.**

2. This application is filed on behalf of
☐ a small entity.

3. Pursuant to 37 C.F.R. § 1.17(c), the fee for filing the Appeal Brief is:
☐ small entity $165.00
☒ other than small entity $330.00
Appeal Brief fee due **$330.00**
☒ Please charge $330.00 to Deposit Account 50-0220.

Respectfully submitted,

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Patricia Lewis
#15/Supp
Appeal
Brief
3.2.04

Attorney's Docket No. 9025-7 PATENT

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APPELLANTS' SUPPLEMENTAL BRIEF ON APPEAL UNDER 37 C.F.R. §1.192

Sir:

This Supplemental Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed December 19, 2003, and supplements Appellants' Appeal Brief filed on July 15, 2003.

Real Party In Interest

The real party in interest is assignee ZyCare, Inc. (formerly named Healthware Corporation), Chapel Hill, North Carolina.

Related Appeals

Appellants are aware of no appeals or interferences that would be affected by the present appeal.

Status of Claims

Appellants appeal the second final rejection of Claims 1-43 which, as of the filing date of this Brief, remain under consideration. The attached Appendix A presents the claims at issue as finally rejected in the second Final Office Action of October 3, 2003 ("Second Final Action").

State of Amendments

The attached Appendix A presents the claims as amended by the Amendment of December 30, 2002. These Amendments were entered.

Summary of the Invention

The present invention provides apparatus and methods that allow a patient to self-monitor disease therapy (*e.g.*, anti-coagulation therapy) and other potentially important variables without requiring the patient to visit a healthcare provider. Typically, disease therapy includes a medication regimen (*e.g.*, warfarin for anticoagulation therapy) and test regimens for monitoring the efficacy or toxicity of the medication dosing regimen. In rehabilitation and wellness promotion the prescription may include exercises and assessment could involve measurement of physical conditioning, range of motion, strength, endurance, rigidity, fine motor control, tremors, and the like. These can be monitored remotely and algorithmically adjusted using prescribed software routines. Exemplary test regimens for diseases include prothrombin time (PT) test for anticoagulation, white blood cell count in cancer chemotherapy patients, potassium or bicarbonate in patients with renal failure, blood pressure in hypertension, heart rate recovering in physical conditioning, depression rating scores or neuropsychological test performance in depression, and pain rating scales in chronic pain, for example. (Specification, Page 7, Line 3 - Page 8, Line 32).

A patient apparatus (*i.e.*, an apparatus utilized by a patient according to the present invention) is configured to receive and analyze information regarding patient compliance with medication and test regimens. A patient apparatus according to the present invention is also configured to receive information or data from a patient concerning supra-therapeutic and sub-therapeutic conditions, signs, symptoms or test results. This same patient apparatus may also be configured to obtain data from the patient on factors which could impact ongoing therapies, such as data concerning diet, exercise, sleep, stress, illness, vitamin and other medication usage. The type of data which the patient apparatus may receive from a patient could include, but would not be limited to, physiological, pathophysiological, biological, psychological, neuropsychological (cognitive performance), behavioral data and/or specific knowledge assessments. For example, a patient can provide information or data regarding mood status, reaction times, tasks measuring divided attention or concentration, or symptoms

the patient may be experiencing, along with changes in diet, exercise, stress or other medications. (Specification, Page 8, Line 33 - Page 9, Line 22).

A patient apparatus according to the present invention can also actively promote compliance with the prescribed treatment regimens using alarm-based initiation of routines which prompt the patient to initiate self-assessment or self-treatment protocols. Software routines in the device or managed through the device and initiated via hardware alarms or communications from remotely connected devices, servers or services can engage the patient in creative ways and help maintain motivation, initiation and completion of self-care regimens. (Specification, Page 9, Lines 23-33).

Utilizing the received patient data, a patient apparatus can modify a medication regimen using an algorithm contained within the apparatus. The apparatus can communicate the modified medication regimen to the patient and to third parties, such as remotely located healthcare providers. The apparatus can prompt a patient when to perform various types of self-assessments and home self-testing to provide data, directed towards monitoring the efficacy of a medication. In addition, the apparatus can prompt a patient to seek medical attention when so warranted. A patient apparatus according to the present invention can also automatically communicate patient information to a healthcare provider (or other third party) if the patient apparatus determines that symptoms that a patient is experiencing are above a severity threshold level. (Specification, Page 9, Line 34 - Page 10, Line 16).

According to another embodiment of the present invention, a patient apparatus for monitoring and modifying disease therapy can communicate directly with a remotely located data processing system that is configured to analyze data transmitted from the patient apparatus substantially simultaneously with the transmission thereof to identify emergency medical conditions requiring immediate medical attention. In response to identifying an emergency medical condition, treatment information may be automatically communicated to the respective patient apparatus while communications are still established. (Specification, Page 10, Lines 17-28).

Issues

1. Are independent Claims 1 and 10 properly rejected under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 6,302,844 to Walker *et al.* (hereinafter "Walker") in view of United States Patent No. 6,161,095 to Brown (hereinafter "Brown") and

Appellants' alleged admission in the Background of the Invention section of the present application?

2. Are independent Claims 29 and 37 properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker in view of Brown?

3. Are Claims 19-28 properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker in view of Brown and Appellants' alleged admission in the Background of the Invention section of the present application, and further in view of United States Patent No. 6,024,699 to Surwit *et al.* (hereinafter "Surwit").

Grouping of Claims

Claims 1-43 stand rejected as obvious under 35 U.S.C. § 103 (a). For the purposes of this appeal, Appellants submit that Claims 1-43 do not stand or fall together.

Arguments

I. Introduction

Each of the claims of the present application stands rejected as obvious under 35 U.S.C. § 103(a). A determination under §103 that an invention would have been obvious to someone of ordinary skill in the art is a conclusion of law based on fact. *Panduit Corp. v. Dennison Mfg. Co.* 810 F.2d 1593, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 107 S.Ct. 2187. After the involved facts are determined, the decision maker must then make the legal determination of whether the claimed invention as a whole would have been obvious to a person having ordinary skill in the art at the time the invention was unknown, and just before it was made. *Id.* at 1596. The United States Patent and Trademark Office (USPTO) has the initial burden under § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

To establish a *prima facie* case of obviousness, the prior art reference or references when combined must teach or suggest **all** the recitations of the claims, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests

the desirability of the combination. M.P.E.P. § 2143.01(citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990)). As emphasized by the Court of Appeals for the Federal Circuit, to support combining references, evidence of a suggestion, teaching, or motivation to combine must be **clear and particular**, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). In an even more recent decision, the Court of Appeals for the Federal Circuit has stated that, to support combining or modifying references, there must be **particular** evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

Furthermore, as recently stated by the Federal Circuit with regard to the selection and combination of references:

> This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion....

In re Sang Su Lee, 277 F.3d 1338, 1343 (Fed. Cir. 2002).

Appellants respectfully submit that the pending claims are patentable over the cited references because the cited combination fails to disclose or suggest the recitations of the pending claims and the reasoning behind such combination has not been established. The patentability of the pending claims is discussed in detail hereinafter.

II. Independent Claims 1, 10, 29 and 37 Are Patentable Over the Cited References

Appellants' independent Claim 1 recites a method of monitoring anticoagulation therapy of a patient, comprising the following steps ***performed by a portable apparatus***:

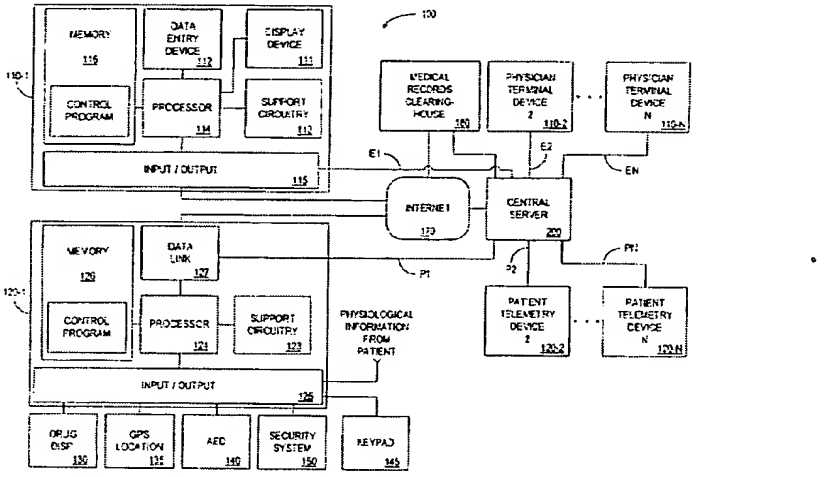
> ***receiving data from a patient at a portable apparatus***, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;
>
> ***assessing severity of the received patient data via the portable apparatus***;
>
> ***prompting the patient to perform a patient-administered coagulation test, via the portable apparatus***, if the received patient data are assessed to be above a threshold severity level;
>
> ***receiving coagulation test results from the patient-administered test at the portable apparatus***; and
>
> ***communicating the received coagulation test results of the patient-administered test from the portable apparatus to a healthcare provider via a communications network.***

Independent Claims 10, 29 and 37 each contain similar recitations.

A. Walker

Walker describes a method and apparatus for analyzing data from remote monitoring equipment, such as a patient telemetry device, and determining (i) if an anomaly exists, (ii) if an anomaly does exist, what kind of action should be taken, and (iii) if a physician should be contacted, which one. The Walker method comprises the steps of: receiving representative data that represents at least one physiological parameter of a patient; determining whether the received data is indicative of a physiological anomaly; selecting at least one expert to provide an expert opinion regarding the indicated anomaly; communicating, to the at least one selected expert, the physiological representative data, including the determined anomaly; and receiving, from at least one selected expert, a diagnosis of the anomaly. The Walker system comprises: a monitor, for monitoring at least one parameter associated with an entity and communicating data representing the at least one entity parameter; and a controller, responsive to the data representing the at least one entity parameter, for determining whether anomalous entity operational parameters are present and, in the case of anomalous entity operational parameters being present, procuring a diagnosis from at least one of a predetermined number of experts." (Walker, Summary of Invention, Col. 1, Lines 65 - Col. 2, Line 27).

Fig. 1 of Walker is reproduced below and illustrates the patient care diagnosis delivery system of Walker.



As set forth in Walker at Col. 4, Lines 7 - Col. 6, Line 34, the Walker system 100 includes a plurality of physician terminal devices 110-1 through 110-N, a central server 200 and a plurality of patient telemetry devices 120-1 through 120-N. Each of the patient telemetry devices 120-1 through 120-N is capable of monitoring at least one physiological parameter of a patient and communicating data representative of the monitored parameter to the central server 200 via respective data paths P1 through PN. The patient telemetry device may comprise a known device capable of monitoring patient data, transmitting that data to the central server and, optionally, receiving data from the central server 200.

The central server 200 examines the communicated data to determine if the at least one physiological parameter is within appropriate or "normal" parameter boundaries. If the data is not within the appropriate boundary, the central server 200 determines if an event or medical anomaly (*e.g.*, cardiac arrest or other condition) may be occurring. If such a determination is made, then the central server 200 communicates an offer to one or more of the physician terminal devices via respective data paths E1 through EN.

Each physician terminal device 110 is associated with at least one respective expert, such as physician(s), nurse(s), and other experts. A physician receiving an offer accepts that offer by communicating an acceptance message to the central server 200 via the physician terminal device 110 or another means (*e.g.*, telephone, computer network and the like). The central server then decides which one (or more than one) of the accepted offers will be confirmed by sending a confirmation signal to the physician via, *e.g.*, the respective physician terminal device(s). The physician terminal device may comprise a known device capable of

receiving information from the central server and, optionally, transmitting information to the central server 200. For example, a pager, a personal digital assistant (PDA) or a cellular telephone may be utilized for this purpose.

In one embodiment, the physiological information received from the patient is merely converted into a digital information stream, either compressed or uncompressed, and transmitted directly to the central server 200. That is, the patient telemetry device does not perform any analysis of the physiological data. The data is merely passed to the central server 200.

In another embodiment, the processor 124 performs an analysis of the received physiological information to determine if, for example, monitored parameters of the patient are within appropriate boundaries. For example, the processor 124 may be programmed (via a control program within the memory 126) to issue an alert to the central server 200 in the event of a patient heart rate exceeding an upper threshold level or dropping below a lower threshold level.

In another embodiment, the patient telemetry device 120-1 and central server 200 communicate bi-directionally. In this embodiment, parameter threshold levels are optionally updated via the data link (P1-PN) or other means (*e.g.*, via an internet or telephone connection) such that patient monitoring may be calibrated to the changing needs of a patient. For example, if a patient is about to exercise, it is quite likely that the measured heart rate will increase. Therefore, the patient may communicate this fact to the central server 200 via a patient control signal produced using the key pad 145. Bi-directional communication may be effected via the internet 170 or other communications medium.

In another embodiment utilizing bi-directional communication with the central server 200, the patient telemetry device 120-1 is associated with a drug dispensing device 130. In this embodiment, the central server 200 may be used to control the dispensing of drugs to the patient via the drug dispensing device 130. For example, in the case of a patient exhibiting physiological information indicative of cardiac arrest, the central server 200 may cause the drug dispensing device 130 to dispense medication tending to reduce or mitigate any harm to the patient due to the event. In the case of local analysis by the patient telemetry device 120, the decision to dispense medication may be made locally.

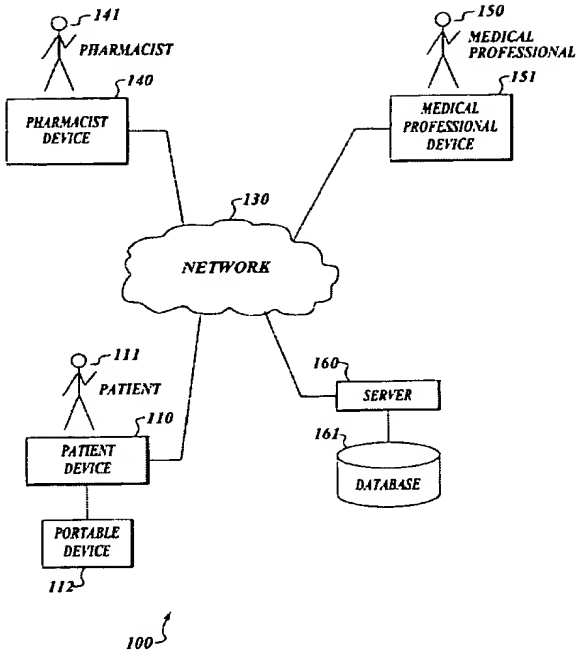
In another embodiment utilizing bi-directional communication with the central server 200, the patient telemetry device 120 is associated with an automatic external defibrillator

(AED) 140. In the event of the physiological information of the patient being indicative of, *e.g.*, a ventricular fibrillation, a central server or decision may indicate that defibrillator is appropriate. In this case, the central server or patient telemetry device causes the automatic external defibrillator to enter an active mode of operation. Present automatic external defibrillators include monitoring capabilities such that they do not administer an electric shock to a patient unless such an electric shock is warranted. That is, present automatic external defibrillators perform monitoring operations to confirm the need for a defibrillator. Such functionality may optionally be incorporated into the patient telemetry device 120. (Walker, Col. 4, Lines 7 - Col. 6, Line 34).

B. Brown

Brown describes a method and system for interaction with a community of individuals, relating to compliance with and effectiveness of treatment regimens, including supply and use of pharmaceuticals, using a protocol or other intelligent message which acts in place of a service provider and which is capable of collecting or imparting information to patients in place thereof. Individuals interact with the protocol or intelligent message to provide assistance in all aspects of treatment regimen compliance, data collection, supply or delivery, review and modification. These aspects can include (1) reminders regarding compliance with a selected treatment regimen for medication, physical therapy, psychological therapy, self-improvement, or some combination thereof, (2) data collection of facts regarding patient compliance, symptomology, possible drug interactions or side effects of medication if required by the treatment regimen, and other facts relevant to evaluation and possible modification of the treatment regimen; (3) networked integration with workstations for medical professionals to automate approvals and modifications, and refills and delivery of medication if required by the treatment regimen. (Brown, Col. 2, Line 53 - Col. 3, Line 6).

Fig. 1 of Brown is illustrated below:



The Brown system 100 monitors compliance with a treatment regimen using a protocol or other intelligent message which acts in place of a service provider to collect and impart information relevant to the treatment regimen, including a patient device 110, a pharmacist device 140, a medical professional device 150, and a server device 160. The devices are coupled using a communication network 130, and a portable device 112 which can be coupled to the patient device 110 to receive information regarding the treatment regimen and send feedback from the patient 111 responsive thereto. The portable device 112 of Brown includes a coupling element 113 for coupling the portable device 112 to the patient device 110, a memory element 114, a processor chip 115 including a clock circuit 116, a presentation element 117, and a patient feedback input element 118.

A service provider determines a treatment regimen for selected patients 111 and a protocol to be followed by their portable devices 112 to assist the patients 111 in following the treatment regimen. The service provider sends the treatment regimen and protocol to the server device 160 where it is recorded in the database 161. The server device 160 sends the treatment regimen and protocol information to the patient device 110, and optionally to the pharmacist device 140 and the medical professional device 150.

The portable device 112 is coupled to the patient device 110 using the coupling element 113. While coupled, the treatment regimen and protocol information received by the

patient device 110 is sent to the portable device 112 and recorded in the memory 114. After the treatment regimen and protocol information is recorded in the memory 114, the portable device 112 can be uncoupled from the patient device 110 and taken with the patient 110 to locations relatively or logically remote from the patient device 110. When the patient 111 is due to perform an act according to the treatment regimen, the portable device 112 uses the presentation element 117 to provide a reminder message instructing the patient 111 to perform that act. The patient 111 performs the indicated act and enters a message into the portable device 112 confirming performance of the act using the patient feedback input element 118. Operation of the patient feedback input element 118 causes the processor chip 115 to cancel the reminder message, check the clock 116, and record the time and fact of performance in the memory 114. (Brown, Col. 4, Line 35 - Col. 5, Line 30).

Brown defines an "act" to be: "compliance with a medication regimen including, without limitation, obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill ... pursuant to a physical therapy regimen including, without limitation, exercising, stretching, changing position, or changing work routine; pursuant to a psychological therapy regimen including, without limitation, repeating an affirmation, meditation, self-hypnosis or other mental activity; or pursuant to a self-help regimen or other type of treatment regimen such as weight loss including, without limitation, drinking water or eating a snack." (Brown, Col. 5, Lines 9-23).

C. Appellants' Background of Invention

The Background of Invention section from Appellants' patent application is set forth below in its entirety:

> Chronic disease management conventionally involves routinely monitoring patients who suffer from chronic disease to identify disease-related health problems before they become medically severe. Routine monitoring is also required in patients undergoing various forms of rehabilitation or primary prevention such as programs designed to promote healthy diet and exercise behavior. Disease management and prevention may also involve monitoring exercise and diet patterns of patients, as well as adherence to and adjustments of prescribed medicine. The management of chronic disease also often involves continuous treatment of a disease process with one or more medicines. Many of these medications have a relatively narrow therapeutic window; that is, there is a narrow range of medication dosages that provide optimal therapeutic effect without producing undesirable and potentially dangerous side effects. Other, often behavioral, factors such as illness, or changes in sleep, vitamins,

diet, exercise, stress, menstrual cycles, etc. can impact the efficacy, absorption, dissipation, bioavailability and hence optimal dosing requirements of medication. Additionally, due to comorbid or co-occurring diseases or intercurrent illness, there are risks related to potential medication interactions that can also affect the efficacy dosing requirements of one or more of the medications used in treatment. Ideally, the effects of medication should be continuously monitored in order to insure that the patient is deriving maximal therapeutic benefit without suffering the effects of overmedication or from potentially dangerous interactions.

Most patient assessment of the efficacy of self-administered treatment programs such as medication regimens, rehabilitative recovery or primary prevention occurs in the offices of healthcare professionals. Unfortunately this is both time-consuming and expensive, and can only partially deal with issues related to timeliness and compliance. To overcome the disadvantages of requiring patients to visit a physician's office for assessment of their disease or condition, various health care organizations have implemented programs where case managers (*i.e.*, persons with some level of medical training) telephone patients periodically to obtain patient data and to coordinate care. Unfortunately, with often hundreds of patients per case manager, personal contact with individual patients on a daily or even regular basis may be difficult. In addition, personal contact with individual patients on a regular basis may be somewhat expensive. Accordingly, case managers using conventional management techniques may not be able to monitor, adjust or promote a patient's medication dosage or other treatment regimen as often as desirable or necessary.

Another approach used in chronic disease management involves automated voice messaging (AVM) services, wherein patients receive regular telephone calls providing various educational and motivational messages from case managers. Exemplary messages may include reminding a patient of a scheduled physician visit. Some AVM services involve one-way communication, wherein a recorded message is delivered to a patient, but no information is obtained from the patient. As a result, the medical condition of a patient may not be available unless the patient is examined in-person by a physician.

AVM services involving two-way communications may allow patients to respond to AVM telephone queries via a touch tone telephone. Information received from patients may be reviewed by a case manager (CM). The CM then may identify which patients require callbacks for gathering more detailed information, discussing problems, or providing further information. Unfortunately, AVM services involving two-way communications may require some level of human intervention to identify patients with medically severe conditions that require immediate medical attention, such as a change in warfarin or insulin dosage. Chronic disease management via AVM has another drawback in that delays may occur between the identification of a patient with a medically severe condition and actual treatment of the condition.

In order to assist the physician and CM in following a patient with chronic disease, home monitoring devices have been developed and marketed that can collect physiologic data and report this data back to the physician. Examples of such devices include home blood glucose monitors, home blood pressure monitors, home peek-flow monitors for asthma, and home coagulation time monitors for patients undergoing anticoagulation therapy. While these systems can collect physiologic data at home, they do not provide direct guidance to the patient on need changes in chronic

medication dosing. They also do not provide a convenient way for physicians to use the data generated to cost-effectively manage patients.

In addition to case managers, AVMs, and home diagnostic devices, several systems have been devised that collect disease-related data at home and transmit them to a central location where the data can be analyzed by a physician or other healthcare professionals. Such systems include DiabCare (Roche Diagnostics), The Buddy System, Health Hero, and LifeChart. Some of these systems directly interface with home physiologic monitors (*e.g.*, DiabCare and LifeChart) as described above. However, all of these systems simply collect data from remotely-located patients and present the data in summary form. They do not attempt to help the physician or health care provider prioritize patients in need of attention, recommend actions to ameliorate the patient's condition, or give information back to the patient about what he or she should do in the event the a change in the therapy regimen in indicated.

One system that has attempted to automate disease management for insulin therapy in diabetes mellitus is the Diacare® System, described in U.S. Patent No. 4,731,726. Unfortunately, the Diacare® System is narrowly focused on treating diabetic patients using insulin, and lacks many of the important features of a system that would be necessary for delivering a wide variety of interventions in a number of medical diseases or conditions such as anticoagulation therapy.

Warfarin and other anticoagulant therapies are indicated for conditions involving the increased likelihood of fibrin clot (thrombosis). These thromboses may increase the likelihood of stroke, myocardial infarctions or other cardiovascular events. Anticoagulant therapies interfere with or decrease the ability of the body to form a fibrin clot (thrombosis). Since under-medication can result in a thrombosis, and overmedication can result in potentially disastrous hemorrhagic complications, all of these therapies need to be very closely monitored. Examples of these therapies and the types of tests used to monitor them are shown in Table 1 below:

Table 1 - Anticoagulation Therapies & Tests

THERAPY	TEST
Warfarin and other vitamin K antagonists	Prothrombin (PT)
Heparin and similar glucosaminoglycans	Partial Thromboplastin Time (PTT)
	Activated Clotting Time (ACT)
	Specific heparin or low low molecular weight heparin assays
Direct thrombin inhibitors (*e.g.*, hirutin, melagatgran)	Ecarin clotting time (ECT)
	Thrombin clotting time
	PT or PTT

PT or other coagulation tests (listed in Table 1) and regular visits to the physician or clinic are needed to monitor anticoagulation therapy. Anticoagulation therapy is a highly individualized matter that should be monitored closely. Numerous factors, alone or in combination, including travel, changes in diet, environment,

physical state and medication may influence response of a patient to anticoagulants. As such, anticoagulant dosage should be controlled by periodic determinations of prothrombin time (PT)/International Normalized Ratio (INR) or other suitable coagulation tests.

Coagulation tests and regular visits to the physician or clinic are typically required to effectively monitor anticoagulation therapy. Unfortunately, regular visits to a physician or clinic can be expensive and inconvenient. In addition, patients may be required to attend training prior to being allowed to self-administer medication and testing regimens. Such training may be too complex and/or cost-prohibitive for many patients.

D. The Cited References Do Not Establish Obviousness

The cited references, alone or combined, fail to teach or suggest *all* the recitations of independent Claim 1. Neither Walker nor Brown nor the Background of Invention section of Appellants' patent application teaches or suggests a portable apparatus configured to perform all of the method steps of Claim 1. For example, neither Walker nor Brown nor the Background of Invention section of Appellants' patent application teaches or suggests a portable apparatus that ***assesses severity of data received from a patient***. Moreover, neither Walker nor Brown nor the Background of Invention section of Appellants' patent application teaches or suggests ***prompting the patient to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level*** via the portable apparatus. Furthermore, the Second Final Action concedes that the primary reference, Walker, does not disclose Appellants' recited element "prompting the patient to perform a patient-administered coagulation test." (Second Final Action , Page 4). The Second Final Action further concedes that Walker fails to disclose a portable apparatus (Second Final Action, Page 5).

In support of its obviousness rejection of independent Claims 1 and 10, the Second Final Action makes the following arguments:

1) Walker discloses "if monitored parameters are not within appropriate boundaries, the telemetry device decides locally to dispense drugs in the case of a patient exhibiting physiological information indicative of cardiac arrest, wherein the medication reduces or mitigates any harm to the patient due to the event, or instructing the patient to take insulin, wherein if the blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted ... it is noted that the telemetry device of Walker is performing analysis locally, and is thus either dispensing a drug or instructing a patient to perform an action in response to the analysis which are both forms of 'prompting' the patient." (Second Final Action, Page 4).

2) Appellants disclose "in the background of the invention that home monitoring devices have been developed and marketed to collect physiologic data and report the data to a physician, wherein the devices include home coagulation time monitors for patients undergoing anticoagulation therapy." (Second Final Action, Pages 6-7).

The Second Final Action then concludes from the above arguments that "it would be obvious to a person of ordinary skill in the art to include monitoring the aforementioned therapies and tests disclosed in the background of the invention within the method taught collectively by Walker and Brown with the motivation of increasing patient compliance with complex treatment regimens and reducing the number of potential side effects by allowing for remote monitoring of treatment regimens." (Second Final Action, Page 7).

The Second Final Action appears to be arguing that the primary reference, Walker, teaches prompting a patient to perform an action, specifically a patient-administered coagulation test, if monitored parameters are not within appropriate boundaries, even though the Second Final Action expressly states that Walker "does not specifically recite 'prompting a patient to perform a test'" (Second Final Action, Page 4).

Walker describes issuing an alert to the central server 200 in the event of a patient heart rate exceeding an upper threshold level or dropping below a lower threshold level. (Walker, Col. 5, Lines 58-66). Walker also describes a patient telemetry device capable of local analysis that can make a decision to dispense medication via a drug dispensing device 130. However, neither of these features teaches or suggests ***prompting a patient to perform a test***, and ***specifically a coagulation test***, if data received from a patient is above a threshold severity level.

The Second Final Action appears to rely on the Background of the Invention section in Appellants' patent application, which describes coagulation tests such as prothrombin, for providing the suggestion or motivation for a portable device to prompt a patient to perform a coagulation test if data received from a patient is above a threshold severity level. The Second Final Action, in piece-meal fashion, then concludes that it would be obvious to combine the references and to provide a portable apparatus that prompts a patient to perform a coagulation test if data received from a patient is above a threshold severity level.

Neither Walker nor Brown teaches or suggests a portable apparatus configured to perform all of the method steps of Claim 1. In fact, the Second Final Action states that "Walker fails to expressly disclose a portable apparatus." (Second Final Action, Page 5). Neither Walker or Brown teaches or suggests a portable apparatus that ***assesses severity of***

data received from a patient. Moreover, neither Walker or Brown teaches or suggests ***prompting the patient to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level*** via the portable apparatus. The mere fact that coagulation tests exist, as described in the Background of the Invention section of Appellants' patent application, does not overcome the deficiencies of the primary and secondary references, Walker and Brown.

Brown provides a very detailed, specific list of patient acts as follows: "compliance with a medication regimen including, without limitation, obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill ... pursuant to a physical therapy regimen including, without limitation, exercising, stretching, changing position, or changing work routine; pursuant to a psychological therapy regimen including, without limitation, repeating an affirmation, meditation, self-hypnosis or other mental activity; or pursuant to a self-help regimen or other type of treatment regimen such as weight loss including, without limitation, drinking water or eating a snack." (Brown, Col. 5, Lines 9-23). There is no mention or suggestion of a patient-administered test of any kind in this detailed, specific list. Specifically, there is no mention or suggestion of a patient-administered coagulation test.

Because neither Walker nor Brown nor the Background of the Invention section of Appellants' patent application teaches or suggests a portable apparatus that performs all of the recited elements of Claim 1 (*e.g.*, assessing severity of received patient data; prompting a patient to perform a coagulation test if data is assessed to be above a threshold severity level; receiving coagulation test results from patient; communicating coagulation test results to a healthcare provider), Appellants respectfully submit that Claim 1, and all claims depending therefrom, are not rendered obvious. For at least the same reasons, independent Claims 10, 19, 29 and 37, and all claims depending therefrom, are also not rendered obvious. Appellants further submit that dependent Claims 2-9, 11-18, 30-36 and 38-43 are patentable at least per the patentability of the independent base claims from which they depend.

III. Claims 19-28 Are Patentable Over the Cited References

Claims 19-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker in view of Brown and the Background of the Invention section of Appellants' patent

application, and further in view of Surwit. However, Surwit cannot be relied on as prior art in an obviousness rejection of Appellants' application. In pertinent part, Section 4807 of the American Inventors Protection Action of 1999, which was enacted November 29, 1999, amended Section 103(c) to recite:

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f) and (g) of Section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. 35 U.S.C. § 103(c).

Furthermore, Section 4807 states that the amendment "shall apply to any application for patent filed on or after the date of the enactment of this Act." S 1948 IS Section 4807.

Surwit issued on February 15, 2000, and was filed on March 13, 1998. Therefore, Surwit is only prior art under 35 U.S.C. § 102(e). Furthermore, Appellants' application and Surwit are commonly owned. Surwit is assigned to Healthware Corporation, 3804 Sweeten Creek Road, Chapel Hill, North Carolina. Appellants' patent application is assigned to the same entity, Healthware Corporation, 3804 Sweeten Creek Road, Chapel Hill, North Carolina. A copy of the recorded assignment for Appellants' patent application was recorded in the U.S. Patent and Trademark Office at Reel 010743/Frame 0860 and is attached hereto at Appendix B. On December 12, 2000, the name of Healthware Corporation was changed to ZyCare, Inc., and this was recorded in the U.S. Patent and Trademark Office at Reel 012815/Frame 0242. A copy of the recorded name change is attached hereto at Appendix C.

Because Surwit and Appellants' patent application are commonly owned by the same entity, ZyCare, Inc. (formerly named Healthware Corporation), Surwit cannot be relied on as prior art in an obviousness rejection of this application which was filed after November 29, 1999. Appellants respectfully submit that obviousness rejections of Claims 19-28 based on Surwit are improper.

IV. Various Dependent Claims Are Independently Patentable

As discussed above, dependent Claims 2-10, 11-18, 30-36 and 38-43 are patentable per the patentability of the independent base claims from which they depend. Many of the dependent claims are also independently patentable.

For example, dependent Claim 5 recites the step of receiving at the portable apparatus information from the patient about patient compliance with the patient-administered

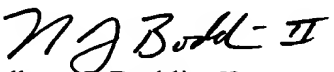
medication and coagulation test regimens during a preceding time period. Claim 5 is independently patentable in that none of the cited references teaches or suggests receiving at a portable apparatus information from a patient about patient compliance with patient-administered medication and coagulation test regimens during a preceding time period. For at least the same reason, Claims 14, 33 and 41 are independently patentable.

As another example, dependent Claim 9 recites "wherein the received patient data comprises at least one of information about hemorrhagic symptoms experienced by the patient and information about non-hemorrhagic symptoms experienced by the patient." Claim 9 is independently patentable in that none of the cited references teaches or suggests receiving at a portable apparatus information from a patient about hemorrhagic symptoms or non-hemorrhagic symptoms experienced by a patient. For at least the same reason, Claim 18 is independently patentable.

V. Conclusion

In light of the above discussion and the discussion in the Appeal Brief filed December 19, 2003, Appellants submit that each of the pending claims is patentable over the cited references and, therefore, request reversal of the rejections of Claims 1-43.

Respectfully submitted,



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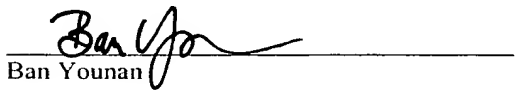

Ban Younan

APPENDIX A

1. A method of monitoring anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, wherein the apparatus is configured to receive and analyze information regarding patient compliance with the patient-administered medication and coagulation test regimens, and wherein the apparatus is configured to modify the patient-administered medication and coagulation test regimens, the method comprising the following steps performed by a portable apparatus:

receiving data from a patient at a portable apparatus, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

assessing severity of the received patient data via the portable apparatus;

prompting the patient to perform a patient-administered coagulation test, via the portable apparatus, if the received patient data are assessed to be above a threshold severity level;

receiving coagulation test results from the patient-administered test at the portable apparatus; and

communicating the received coagulation test results of the patient-administered test from the portable apparatus to a healthcare provider via a communications network.

2. The method according to Claim 1 further comprising the steps of:

assessing severity of the received coagulation test results from the patient-administered coagulation test via the portable apparatus;

modifying the patient-administered medication regimen via the portable apparatus if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and

communicating the modified patient-administered medication regimen to the patient.

3. The method according to Claim 2 further comprising the step of communicating the modified patient-administered medication regimen from the portable apparatus to a healthcare provider via a communications network.

4. The method according to Claim 2 further comprising the step of communicating the modified patient-administered medication regimen from the portable apparatus to a remotely located data processing system via a communications network.

5. The method according to Claim 1 further comprising the step of receiving at the portable apparatus information from the patient about patient compliance with the patient-administered medication and coagulation test regimens during a preceding time period.

6. The method according to Claim 1 further comprising the step of automatically communicating the received patient data from the portable apparatus to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

7. The method according to Claim 6 wherein the step of automatically communicating the received patient data to a healthcare provider comprises paging the healthcare provider.

8. The method according to Claim 4 further comprising the step of communicating information regarding medication dosage from the portable apparatus to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.

9. The method according to Claim 1 wherein the received patient data comprises at least one of information about hemorrhagic symptoms experienced by the patient and information about non-hemorrhagic symptoms experienced by the patient.

10. A portable apparatus that monitors anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, comprising:

a processor;

a user interface in communication with the processor;

computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

computer code executable by the processor that assesses severity of the received patient data;

computer code executable by the processor that prompts a patient via the user interface to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level;

computer code executable by the processor that receives and stores coagulation test results from the patient-administered coagulation test;

computer code executable by the processor that communicates the received coagulation test results from the patient-administered coagulation test to a healthcare provider via a communications network.

11. The portable apparatus according to Claim 10 further comprising:

computer code executable by the processor that assesses severity of the received coagulation test results from the patient-administered coagulation test; computer

code executable by the processor that modifies the patient-administered medication regimen if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and

computer code executable by the processor that communicates the modified patient-administered medication regimen to the patient.

12. The portable apparatus according to Claim 11 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a healthcare provider via a communications network.

13. The portable apparatus according to Claim 11 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a remotely located data processing system via a communications network.

14. The portable apparatus according to Claim 10 further comprising computer code executable by the processor that receives and stores information from a patient about patient compliance with the patient-administered medication and coagulation test regimens during a preceding time period.

15. The portable apparatus according to Claim 10 further comprising computer code executable by the processor that automatically communicates the received patient data to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

16. The portable apparatus according to Claim 15 wherein the computer code that automatically communicates the received patient data to a healthcare provider comprises computer code that sends a paging signal to a healthcare provider.

17. The portable apparatus according to Claim 13 further comprising computer code executable by the processor that communicates information regarding

medication dosage to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.

18. The portable apparatus according to Claim 10 wherein the received patient data comprises at least one of information about hemorrhagic symptoms experienced by the patient and information about non-hemorrhagic symptoms experienced by the patient.

19. A system that monitors anticoagulation therapy of a patient, wherein the anticoagulation therapy includes a patient-administered medication regimen selected from the group consisting of warfarin and vitamin K antagonists, heparin and glucosaminoglycans, and direct thrombin inhibitors, and a patient-administered regimen for a coagulation test that monitors efficacy of the medication regimen, wherein the coagulation test is selected from the group consisting of prothrombin time (PT) test, partial thromboplastin time (PTT) test, activated clotting time (ACT) test, heparin assays, ecarin clotting time (ECT) test, and thrombin clotting time test, wherein the system comprises:

a portable patient apparatus, comprising:

a processor;

a user interface in communication with the processor;

computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

computer code executable by the processor that assesses severity of the received patient data;

computer code executable by the processor that prompts the patient via the user interface to perform a patient-administered coagulation test if the received patient data are assessed to be above a threshold severity level;

computer code executable by the processor that receives and stores coagulation test results from the patient-administered coagulation test; and

computer code executable by the processor that communicates the received coagulation test results from the patient-administered coagulation test to a healthcare provider via a communications network; and

a remotely located data processing system configured to communicate with and receive data from the portable patient apparatus, the remotely located data processing system comprising:

computer code that obtains patient data from the patient apparatus;

computer code that analyzes the obtained patient data from to identify medical conditions of a patient;

computer code that displays identified patient medical conditions for a patient in selectable, prioritized order according to medical severity via a remotely located client in communication with the central data processing system; and

computer code that displays treatment options for treating a selected medical condition for a patient.

20. The system according to Claim 19 wherein the portable patient apparatus further comprises:

computer code executable by the processor that assesses severity of the received coagulation test results from the patient-administered coagulation test;

computer code executable by the processor that modifies the patient-administered medication regimen if the received coagulation test results from the patient-administered coagulation test are assessed to be above a threshold severity level; and

computer code executable by the processor that communicates the modified patient-administered medication regimen to the patient.

21. The system according to Claim 19 further comprising computer code that communicates treatment information from the remotely located data processing system to the patient apparatus.

22. The system according to Claim 21 wherein the computer code that communicates treatment information from the remotely located data processing system to the portable patient apparatus comprises computer code that transmits treatment information via wireless, satellite, telephone, e-mail, AVM or facsimile transmission.

23. The system according to Claim 22 wherein the computer code that communicates treatment information from the remotely located data processing system to the portable patient apparatus comprises computer code that modifies the medication algorithm within the portable patient apparatus.

24. The system according to Claim 19 wherein the computer code that obtains patient data from the portable patient apparatus further comprises:

computer code that analyzes data transmitted from the patient apparatus substantially simultaneously with the transmission thereof to the remotely located data processing system to identify emergency medical conditions requiring immediate medical attention; and

computer code that automatically communicates treatment information to the patient apparatus for an identified emergency medical condition.

25. The system according to Claim 19 wherein the remotely located data processing system further comprises:

computer code that monitors patient usage of medication; and

computer code that orders medication for a patient from a supplier of medication.

26. The system according to Claim 19 wherein the computer code that displays identified patient medical conditions comprises computer code that displays selected ones of the identified patient medical conditions.

27. The system according to Claim 19 wherein the portable patient apparatus further comprises computer code that receives information via the user interface about patient compliance with the patient-administered medication regimen and the patient-administered coagulation test regimen during a preceding time period.

28. The system according to Claim 19 wherein the portable patient apparatus further comprises computer code that communicates information regarding

medication dosage to a patient via the user interface in response to determining that a patient did not comply with the patient-administered medication regimen in a preceding time period.

29. A method of monitoring disease therapy of a patient via a portable patient apparatus, wherein the disease is selected from the group consisting of asthma, cancer chemotherapy, depression, high blood pressure, seizure disorders, and thrombosis, wherein the disease therapy includes a patient-administered medication regimen and a patient-administered regimen for a test that monitors efficacy of the medication regimen, wherein the portable patient apparatus is configured to receive and analyze information regarding patient compliance with the patient-administered medication and test regimens, and wherein the portable patient apparatus is configured to modify the patient-administered medication and test regimens, the method comprising the following steps performed by the apparatus:

receiving data from a patient at a portable patient apparatus, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

assessing severity of the received patient data via the portable patient apparatus;

prompting the patient to perform a patient-administered test if the received patient data are assessed to be above a threshold severity level via the portable patient apparatus;

receiving test results from the patient-administered test at the portable patient apparatus; and

communicating the received test results of the patient-administered test from the portable patient apparatus to a healthcare provider via a communications network.

30. The method according to Claim 29 further comprising the steps of:

assessing severity of the received test results from the patient-administered test via the portable patient apparatus;

modifying the patient-administered medication regimen via the portable patient apparatus if the received test results from the patient-administered test are assessed to be above a threshold severity level; and

communicating the modified patient-administered medication regimen to the patient.

31. The method according to Claim 30 further comprising the step of communicating the modified patient-administered medication regimen from the portable patient apparatus to a healthcare provider via a communications network.

32. The method according to Claim 30 further comprising the step of communicating the modified patient-administered medication regimen from the portable patient apparatus to a remotely located data processing system via a communications network.

33. The method according to Claim 29 further comprising the step of receiving at the portable patient apparatus information from the patient about patient compliance with the patient-administered medication and test regimens during a preceding time period.

34. The method according to Claim 29 further comprising the step of automatically communicating the received patient data from the portable patient apparatus to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

35. The method according to Claim 32 further comprising the step of communicating information regarding medication dosage from the portable patient apparatus to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.

36. The method according to Claim 29 wherein the received patient data further comprises at least one of information about a supra-therapeutic symptom experienced by the patient and information about a sub-therapeutic symptom experienced by the patient.

37. A portable apparatus that monitors disease therapy of a patient, wherein the disease is selected from the group consisting of asthma, cancer chemotherapy, depression, high blood pressure, seizure disorders, and thrombosis, wherein the disease therapy includes a patient-administered medication regimen and a patient-administered regimen for a test that monitors efficacy of the medication regimen, the portable apparatus comprising:

a processor;

a user interface in communication with the processor;

computer code executable by the processor that receives and stores data from a patient, wherein the patient data includes at least one of physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and behavioral data;

computer code executable by the processor that assesses severity of the received patient data;

computer code executable by the processor that prompts the patient via the user interface to perform a patient-administered test if the received patient data are assessed to be above a threshold severity level;

computer code executable by the processor that receives and stores test results from the patient-administered test; and

computer code executable by the processor that communicates the received test results from the patient-administered test to a healthcare provider via a communications network.

38. The portable apparatus according to Claim 37 further comprising:

computer code executable by the processor that assesses severity of the received test results from the patient-administered test;

computer code executable by the processor that modifies the patient-administered medication regimen if the received test results from the patient-administered test are assessed to be above a threshold severity level; and

computer code executable by the processor that communicates the modified patient-administered medication regimen to the patient.

39. The portable apparatus according to Claim 38 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a healthcare provider via a communications network.

40. The portable apparatus according to Claim 38 further comprising computer code executable by the processor that communicates the modified patient-administered medication regimen to a remotely located data processing system via a communications network.

41. The portable apparatus according to Claim 37 further comprising computer code executable by the processor that receives and stores information provided by the patient about patient compliance with the patient-administered medication and test regimens during a preceding time period.

42. The portable apparatus according to Claim 37 further comprising computer code executable by the processor that automatically communicates the received patient data to a healthcare provider via a communications network if patient data are assessed to be above a threshold severity level.

43. The portable apparatus according to Claim 40 further comprising computer code executable by the processor that communicates information regarding medication dosage to the patient in response to determining that the patient did not comply with the medication regimen in the preceding time period.